

MAR 13 2008

K080133

Page 1 of 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of AM Surgical's Mountable Endoscopic Blade.

Submitted By:	A.M. Surgical, Inc.
Date:	January 14, 2008
Contact Person:	Vincent Pascale Phone: 800-437-9653 Fax: 631-980-4369
Proprietary Name:	Mountable Endoscopic Blade
Common Name:	Surgical Knife
Classification Name and Reference:	21 CFR 878.4800, Manual Surgical Instrument for General Use
Device Product Code and Panel Code:	General and Plastic Surgery/EMF

DEVICE INFORMATION

A. INTENDED USES/ INDICATIONS

The Mountable Endoscopic Blade is indicated for use in minimally invasive ligament or fascia release.

- Carpal tunnel release for carpal tunnel syndrome
- Plantar fasciotomy for plantar fasciitis
- Lateral release of the knee for extensor mechanism malalignment
- Forearm fasciotomy for compartment syndrome
- Morton's neuroma for interdigital neuroma
- Gastrocnemius release for heel cord contracture (equinus)

B. DEVICE DESCRIPTION

The Mountable Endoscopic Blade is a device that mounts to a 4mm 30° endoscope.

C. MATERIALS

The blade is manufactured from stainless steel. There is no change in material for the Mountable Endoscopic Blade.

D. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material composition, and design features of the Mountable Endoscopic Blade are substantially equivalent to previously cleared 510(k) Mountable Endoscopic Blade (K982142). The safety and effectiveness of Mountable Endoscopic Blade is adequately supported by the substantial equivalence information provided within this Premarket Notification.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2008

A.M. Surgical, Inc.
% Mr. Vincent Pascale
290 East Main Street, Suite 200
Smithtown, New York 11787

Re: K080133
Trade/Device Name: Mountable Endoscopic Blade
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: II
Product Code: EMF
Dated: March 5, 2008
Received: March 5, 2008

Dear Mr. Pascale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080133

Indications for Use Statement

510(k) Number: Not yet assigned.

Device Name: Mountable Endoscopic Blade

Indications For Use:

The Mountable Endoscopic Blade is indicated for use in minimally invasive ligament or fascia release.

- Carpal tunnel release for carpal tunnel syndrome
- Plantar fasciotomy for plantar fasciitis
- Lateral release of the knee for extensor mechanism malalignment
- Forearm fasciotomy for compartment syndrome
- Morton's neuroma for interdigital neuroma
- Gastrocnemius release for heel cord contracture (equinus)

(Division Sign-Off)

Division of General Restorative
Devices

510(k) Number

Prescription Use X

OR

Over-The Counter Use

(Per 21 CFR 801.109
96)

(Optional Format 1-2-

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number: K080133